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(54) **METHODS FOR CONCOMITANT TREATMENT OF THEOPHYLLINE AND FEBUXOSTAT**

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(58) **Field of Classification Search** None
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,058,614 A	11/1977	Baldwin
4,156,732 A	5/1979	Lang
4,296,122 A	10/1981	Cragoe
4,510,322 A	4/1985	Blaine
4,632,930 A	12/1986	Carini et al.
5,268,386 A	12/1993	Harada et al.
5,358,961 A	10/1994	Lee et al.
5,514,681 A	5/1996	Wren
5,614,520 A	3/1997	Kondo et al.
5,693,818 A	12/1997	Von Unge
5,770,601 A	6/1998	Wren
5,883,137 A	3/1999	King
5,965,625 A	10/1999	King
6,015,829 A	1/2000	Ishibuchi et al.
6,037,344 A	3/2000	Wren
6,225,474 B1	5/2001	Matsumoto et al.
6,281,222 B1	8/2001	Salzman et al.
6,569,862 B1	5/2003	Marban
7,074,816 B2	7/2006	Nakamura et al.
2002/0019360 A1	2/2002	Kivlighn
2002/0187120 A1	12/2002	Holmes-Farley et al.
2003/0039627 A1	2/2003	Holmes-Farley et al.
2003/0186998 A1	10/2003	Marban
2004/0121004 A1	6/2004	Taneja
2004/0122067 A1	6/2004	Zhao

2004/0131676 A1	7/2004	Taneja
2005/0070552 A1	3/2005	Fedida et al.
2006/0040945 A1	2/2006	Smolka et al.
2006/0252808 A1	11/2006	Joseph-Ridge
2007/0167454 A1	7/2007	Lademacher
2008/0269226 A1	10/2008	Lademacher
2009/0042887 A1	2/2009	Lademacher et al.
2009/0124623 A1	5/2009	Lademacher et al.
2010/0311756 A1	12/2010	Zhao
2012/0065207 A1	3/2012	Gunawardhana
2012/0065215 A1	3/2012	Gunawardhana

OTHER PUBLICATIONS

Elenbaas et al., Annals Emergency Medicine, (Feb. 1984), 13(2), pp. 92-96 (Abstract).*

Traymor, K., American Journal Health-System Pharmacy, (Apr. 1, 2009), 66, p. 606.*

Allopurinol Drugdex Drug Evaluations, Thompson MICROMEDEX, 2006, 52 pages.

Antiplatelet Trialists Collaboration et al., Collaborative overview of randomised trials of antiplatelet therapy—I Prevention of death, myocardial infarction, and stroke by prolonged antiplatelet therapy in various categories of patients, BMJ vol. 308, pp. 81-106, Jan. 8, 1994. Anzai et al., Renal Urate Handling: Clinical Relevance of Recent Advances, Current Science Inc. Copyright 2005, pp. 227-234.

Arakawa et al., Allopurinol Hypersensitivity Syndrome Associate with Systemic Cytomegalovirus Infection and Systemic Bacteremia, International Medicine vol. 40, No. 4, pp. 331-335 (Apr. 2001).

Arellano et al., Allopurinol Hypersensitivity Syndrome—A Review, The Annals of Pharmacotherapy, vol. 27, pp. 337-341, Mar. 1993.

Arromdee et al., Epidemiology of Gout—Is the Incidence Rising, the Journal of Rheumatology 2002; 29:11, pp. 2403-2406.

Baker et al., Serum uric acid and cardiovascular disease: Recent Development, and where do they leave us? The American Journal of Medicine, vol. 118 No. 8, pp. 816-826, Aug. 2005.

Becker et al., Clinical Aspects of Monosodium Urate Monohydrate Crystal Deposition Disease (Gout). Rheumatic Disease Clinics of North America—vol. 14, No. 2, pp. 377-395, Aug. 1988.

Becker et al., We can make Gout Management more successful now, Current Opinion in Rheumatology, vol. 20, pp. 167-172, 2008.

Becker, M. et al., “A Phase 3 Randomized, Controlled, Multicenter, Double-Blind Trial (RCT) Comparing Efficacy and Safety of Daily Febuxostat (FEB) and Allopurinol (ALLO) in Subjects with Gout” [abstract]. Amer College Rheum. (2008) Abstract No. L11.

Becker, M.A. et al., A phase 3 study comparing the safety and efficacy of oral febuxostat and allopurinol in subjects with hyperuricemia and gout [abstract]. Arthritis Rheum. Dec. 2004; 50(12):4103-4104. Abstract No. L18.

Becker, M.A. et al., “A safety and efficacy clinical trial of a novel non-purine selective inhibitor of xanthine oxidase, febuxostat in subjects with gout” [abstract]. Ann Rheum Dis. Jul. 2004; 63(Suppl 1):60. Abstract No. OP0007.

Becker, M.A. et al., “Allopurinol intolerant patients treated with febuxostat for 4 years” [abstract]. Arthritis Rheum. Sep. 2006; 54(9 Suppl):S646-S647. Abstract No. 1605.

(Continued)

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(57) **ABSTRACT**

Co-administration of febuxostat and theophylline to a hyperuricemic patient suffering from gout is disclosed.

1 Claim, 1 Drawing Sheet